

**In the United States Court of Federal Claims**

No. 06-522V  
(Filed January 28, 2011)

*****	*	National Childhood Vaccine
	*	Injury Act, 42 U.S.C. §§ 300aa-1
<b>ROBERT VERYZER,</b>	*	- 300aa-34 (2006); petition for
	*	review; proof of causation in
Petitioner,	*	fact; 42 U.S.C. § 300aa-
	*	12(d)(3)(A)(I), findings of fact
v.	*	by special master; Vaccine R.
	*	8(b)(1); <u>Daubert v. Merrell Dow</u>
<b>SECRETARY OF HEALTH</b>	*	<u>Pharm., Inc.</u> , 509 U.S. 579
<b>AND HUMAN SERVICES,</b>	*	(1993); special master's
	*	authority <i>in limine</i> to exclude
Respondent.	*	expert opinions.
	*	
*****	*	

Alan C. Milstein, Pennsauken, NJ, for petitioner.

Voris E. Johnson, Jr., Washington, DC, with whom was Assistant Attorney General Tony West, for respondent.

**MEMORANDUM OPINION AND ORDER**

**MILLER**, Judge.

This case, before the court after argument on petitioner's motion for review of the special master's order of dismissal, involves an examination into the nature and extent of the authority of the office of special masters to admit or exclude expert opinion evidence from the record that Congress contemplated under the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1 - 300aa-34 (2006) (the "Vaccine Act"). On July 17, 2006, petitioner filed a petition in the United States Court of Federal Claims, alleging that he is due compensation under the Vaccine Act for injuries allegedly sustained following a Hepatitis A vaccination. To receive compensation under the Vaccine Act, a petitioner must demonstrate that he was given a vaccine listed on the Vaccine Injury Table, 42 U.S.C. § 300aa-14 (the "Vaccine Injury Table"), and that this vaccine caused him to develop either an injury presumed to have been caused by a vaccination or an "off-Table" injury, i.e., an injury not presumed to have been caused by the vaccines listed in the Vaccine Injury

Table. See 42 U.S.C. § 300aa-11(c). Petitioner pleaded an off-Table injury, which requires proof of causation. 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I).

Special Master Richard B. Abell granted respondent's motions *in limine* excluding from the record petitioner's expert opinions as to causation on the ground that both experts' methodologies and qualifications did not meet the standards for reliability set forth by the United States Supreme Court in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). Shortly thereafter, petitioner moved for a decision based on the written record, pursuant to § 300aa-12(d)(2)(D). The special master denied compensation after concluding that, in the absence of reliable expert opinion, petitioner's medical records and other supporting documentation were insufficient to meet petitioner's burden of proving causation in fact set forth in Althen v. Secretary of Health and Human Services, 418 F.3d 1274 (Fed. Cir. 2005). The issues to be decided are whether the special master had the authority to exclude the opinions of petitioner's experts; if so, whether the special master's decision to do so was an abuse of discretion; and whether the special master's subsequent decision denying compensation was arbitrary, capricious, or an abuse of discretion.

## FACTS

The record on review supports the recitation of facts cited in the special master's order and opinions. Robert Veryzer ("petitioner") was formerly an instructor of business at the University of Florida and was an Associate Professor at the Lally School of Management & Technology, Rensselaer Polytechnic Institute. Petitioner earned a B.A. from Olivet College, an M.B.A. from Michigan State University, and a Ph.D. from the University of Florida. He has authored numerous scholarly articles and a book focusing on business and marketing. On April 25, 2001, at age forty-one, petitioner received both the Hepatitis A and Hepatitis B vaccinations. Veryzer v. Sec'y of Health & Human Servs., No. 06-0522V, 2010 WL 5185485, at \*1 (Fed. Cl. Spec. Mstr. Aug. 9, 2010) ("Veryzer II"). Within hours of the vaccinations, petitioner suffered fever and chills, and within days experienced severe pain and physical injuries, including "complete sexual dysfunction [including] . . . pain in the head of his penis; urethral burning; erectile dysfunction; decreased libido; and insensitivity in his genitals/testicles." Pet. filed July 17, 2006, ¶¶ 17-18 (Fed. Cl. Spec. Mstr.). Petitioner alleges that these injuries caused him to suffer depression, panic attacks, severe anxiety, and suicidal thoughts. Id. ¶ 37. All of these injuries petitioner attributes to his vaccinations. Veryzer II, 2010 WL 5185485, at \*1. Petitioner originally filed a petition in the United States Court of Federal Claims pursuant to 42 U.S.C. § 300aa-11 on September 29, 2003. Petitioner sought compensation due to injuries only caused by the Hepatitis B vaccination, because at the time of petitioner's filing the Hepatitis A vaccine had not been added to the Vaccine Injury Table. Id.; see National Vaccine Injury Compensation Program: Inclusion

of Hepatitis A Vaccines in the Vaccine Injury Table, 69 Fed. Reg. 69,945, 69,945-46 (Dec. 1, 2004) (adding Hepatitis A to Vaccine Injury Table).

Due to difficulty obtaining an expert to testify in support of petitioner's Hepatitis B claim, petitioner on November 2, 2004 withdrew his petition. Veryzer II, 2010 WL 5185485, at \*1; see also 42 U.S.C. § 300aa-12(g), -21(b) (permitting petitioner to withdraw petition if special master has not issued decision within 240 days from date petition was filed). "That case was thus concluded without a final order . . . and without entry of judgment on the petitioner's claim for compensation." Veryzer II, 2010 WL 5185485, at \*2. A month later, on December 1, 2004, Hepatitis A was added to the Vaccine Injury Table. See 69 Fed. Reg. 69,945, 69,945-46. Petitioner filed suit against the vaccine manufacturer, SmithKline Beecham Corporation, in the United States District Court for the Northern District of New York, alleging that both the Hepatitis A and Hepatitis B vaccines caused his injuries. Veryzer II, 2010 WL 5185485, at \*2. The manufacturer demurred, arguing that, because the Hepatitis A vaccine was now included in the Vaccine Injury Table, petitioner was required first to bring his Hepatitis A claim under the Vaccine Act before he could sue the manufacturer. Id. The district court dismissed petitioner's second suit without prejudice. Id.

On July 17, 2006, petitioner filed his current petition in the Court of Federal Claims, claiming entitlement to compensation under the Vaccine Act due to injuries caused by the Hepatitis A vaccine. Pet. at 1, 9. Petitioner's relevant medical records were submitted on March 9, 2007. Petitioner initially obtained a medical expert who opined that the injuries were caused by the Hepatitis B vaccine, not Hepatitis A. Veryzer v. Sec'y of Health & Human Servs., No. 06-0522V, 2008 WL 440298, at \*1 (Fed. Cl. Spec. Mstr. Jan. 30, 2008). On April 6, 2007, petitioner moved to amend his petition to include a claim for the Hepatitis B vaccine, which the special master denied pursuant to 42 U.S.C. § 300aa-11(b)(2) and the doctrine of claim preclusion; petitioner was required to rest his petition on a theory that the Hepatitis A vaccination caused his injuries. Veryzer II, 2010 WL 5185485, at \*2. Petitioner obtained expert reports from Drs. Andrew Moulden, M.D., Ph.D., and Sherri Tenpenny, D.O. Dr. Moulden concluded that petitioner's injuries were the result of the eponymous "Moulden Anoxia Spectra Syndrome," or "M.A.S.S. response," which resulted from the Hepatitis A vaccination and caused neurological, physiological, and functional damage to petitioner. Pet'r's Br. filed Aug. 27, 2008, Ex. 2 at 112, ECF No. 36 (Fed. Cl. Spec. Mstr.) (the "Moulden Report"); see also Veryzer v. Sec'y of Health & Human Servs., No. 06-0522V, 2010 WL 2507791, at \*3 (Fed. Cl. Spec. Mstr. May 19, 2010) ("Veryzer I"). The special master aptly summarized Dr. Moulden's theory, as follows:

Dr. Moulden does not ascribe credibility to the accepted theories typically proffered to explain vaccine injuries, instead believing that, as with

“most people with vaccine-related injuries,” Petitioner actually suffered from the root mechanism of vaccine injury: the MASS response, which he weaves into a pastiche of seemingly unrelated conditions, without limiting to the ones from which Petitioner was affected. According to Dr. Moulden’s report, regardless of the contents of the particular vaccine, they all result initially in the same MASS response, albeit manifesting in sundry injuries such as Autism Spectrum Disorder, Sudden Infant Death Syndrome, Guillain-Barré Syndrome, Gulf War Syndrome, and the heretofore unnamed “Gardasil War Syndrome.” Even in describing the terminal effects of his MASS response . . . Dr. Moulden would not describe its specific activation, onset, or mechanism, demurring that such information “is proprietary level information and will not be disclosed for the purposes of [the] expert report.”

Dr. Moulden stated in his report that “all vaccines are useless—always have been, always will be,” that “vaccinations are the number one cause of chronic disease and disability in otherwise healthy individuals—globally,” and that “all vaccines are causing death, brain damage, ischemic strokes, and chronic illness—to the brain, the body, and to our pets.”

Id. (alterations in original) (citations omitted) (footnotes omitted). Dr. Moulden contends that “[Louis] Pasteur’s germ theory of mammalian disease is both incorrect and inaccurate in that “disease is NOT being caused by ANY particular pathogen or strain of pathogen . . . it is the non-specific immune response to foreign substances [in] the body and blood stream that causes disease—all diseases.” Moulden Report at 90 (ellipsis in original). Dr. Moulden believes that “[t]he entire medical model is both flawed and incorrect” and he states “conclusively” that “vaccinations are neither necessary nor effective in preventing any human disease in any form whatsoever.” Id. at 91.

Dr. Tenpenny’s report, by contrast, lacks the bombast and sweeping historical conclusions associated with Dr. Moulden’s. Dr. Tenpenny concludes a three-page case history by opining that petitioner’s injuries either “could . . . be categorized as a form of acute disseminated encephalomyelitis, or ADEM,” or “undiagnosed [multiple sclerosis (“MS”).” Pet’r’s Br. filed Aug. 27, 2008, Ex. 1 at 5-6, ECF No. 35 (Fed. Cl. Spec. Mstr.) (the “Tenpenny Report”). Dr. Tenpenny cites as support for her MS theory a report from Dr. March Girard, which was filed in support of petitioner’s Hepatitis B claim, and attributes the MS symptoms to the Hepatitis B vaccination. Veryzer I, 2010 WL 2507791, at \*13.

On October 17, 2008, respondent filed two motions *in limine* seeking to exclude the opinions of Drs. Moulden and Tenpenny, arguing that the proffered experts do not satisfy the reliability standard for the admissibility of expert testimony set by the United States Supreme

Court in Daubert, 509 U.S. 579, and by the United States Court of Appeals for the Federal Circuit in Terran v. Secretary of Health and Human Services, 195 F.3d 1302 (Fed. Cir. 1999), and fail to meet the threshold of relevance and reliability set forth in RCFC App. B, Vaccine R. 8(b)(1) (“Vaccine Rule”). <sup>1/</sup> See Veryzer I, 2010 WL 2507791, at \*1.

Respondent argued that the special master had authority to exclude expert opinion testimony *in limine* through the interplay of 42 U.S.C. § 300aa-13(b), Vaccine R. 8, and Daubert and its progeny. Id. at \*3-5. <sup>2/</sup> Respondent faulted Dr. Moulden’s methodology for lack of testing, peer review, or publication, id. at \*6, and characterized the expert’s opinions as “unreliable *ipse dixit*,” that “diverge[] quite obtusely from accepted scientific methodology,” id. at \*3. Respondent challenged the reliability of Dr. Tenpenny’s opinion on the basis of her qualifications, arguing that her medical degree in osteopathy and background in emergency medicine do not qualify her to opine on matters of neurology. Id. at \*12-13 (noting also Dr. Tenpenny’s lack of published, peer-reviewed articles). Petitioner’s “primary defense” of both Drs. Moulden and Tenpenny was that they both “‘employed differential diagnosis in reaching their conclusions,’” which is widely recognized and accepted in the medical community, thereby rendering their methodology reliable. Id. at \*8.

On May 19, 2010, the special master granted both motions *in limine*. The special master framed the initial issue to be decided as whether a special master “has authority to exclude evidence, or whether, on the contrary, it must admit and consider everything filed or propounded by either party.” Veryzer I, 2010 WL 2507791, at \*19. Second, the special master sought to determine the appropriate legal standard for excluding evidence. Id. at \*18. Regarding the first question, the special master concluded that he had authority to exclude proffered evidence. In addition to the Vaccine Rules and case law, the special master relied

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<sup>1/</sup> Vaccine Rule 8, which governs the receipt of evidence by the special masters, provides, in relevant part: “In receiving evidence, the special master will not be bound by common law or statutory rules of evidence but must consider all relevant and reliable evidence governed by principles of fundamental fairness to both parties.” Vaccine R. 8(b)(1).

<sup>2/</sup> Petitioner stipulated that the special master had authority to exclude expert opinion evidence *in limine*. See Veryzer I, 2010 WL 2507791, at \*8 (“On the issue of the legal standard governing the Court in ruling on Respondent’s Motion, Petitioner essentially stipulates to Respondent’s analysis of the case law, from FRE 702, on to Daubert, then to Terran, concluding that ‘Daubert has been held to provide special masters with a helpful analytical framework for assessing the reliability of the evidence presented in vaccine cases.’” (citation omitted)).

on 42 U.S.C. § 300aa-13(b)-(c) as authority. <sup>3/</sup> See Veryzer I, 2010 WL 2507791, at \*18 (“As always, ‘[w]e begin our analysis with the language of the Vaccine Act.’” (quoting Markovich v. Sec’y of Health & Human Servs., 477 F.3d 1353, 1357 (Fed. Cir. 2007))).

The special master summarized the provision as requiring the special master to “consider *all* relevant medical and scientific evidence contained *in the record*, but . . . the record is itself established by the Court [i.e., the special master].” Id. at \*19 (internal quotation marks omitted). Next, the special master emphasized two clauses:

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<sup>3/</sup> 42 U.S.C. § 300aa-13(b)-(c) provides, in relevant part:

(b) Matters to be considered

(1) In determining whether to award compensation to a petitioner . . . the special master or court shall consider, in addition to all other relevant medical and scientific evidence contained in the record—

(A) any diagnosis, conclusion, medical judgment, or autopsy or coroner’s report which is contained in the record regarding the nature, causation, and aggravation of the petitioner’s illness, disability, injury, condition, or death, and

(B) the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.

Any such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court. In evaluating the weight to be afforded to any such diagnosis, conclusion, judgment, test result, report, or summary, the special master or court shall consider the entire record and the course of the injury, disability, illness, or condition until the date of the judgment of the special master or court.

. . . .

(c) “Record” defined

For purposes of this section, the term “record” means the record established by the special masters of the United States Court of Federal Claims in a proceeding on a petition filed under section 300aa-11 of this title.

First, subsection (b)(1) states that the Court must consider all evidence in the medical records, “in addition to all other relevant medical and scientific evidence.” It is within this latter category that expert witness materials are included. To this category, the explicit modifiers “relevant,” “medical,” and “scientific” appear to be preconditions. There is no manifest statutory mandate for the Court to consider expert materials that do not at least facially meet these criteria. Second, the [Vaccine] Act gives explicit authority, in subsection (c), to “establish” the record, and the record thus established is the record that subsection (b) . . . instructs the Court to consider.

Id. at \*19. The special master concluded that subsection (c) grants authority to exclude evidence deemed not relevant. See id. The special master cited Vaccine Rule 8 as “the relevant rule of procedure to effectuate this process.” Id. at \*20.

The special master agreed with respondent’s invocation of Daubert’s evidentiary “gatekeeping” function, reasoning that the Federal Circuit’s opinions in de Bazan v. Secretary of Health and Human Services, 539 F.3d 1347, 1352 n.4 (Fed. Cir. 2008), and Munn v. Secretary of Health and Human Services, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992), “contemplated that exclusion *in limine* is an option, provided it is timely raised and not waived.” Veryzer I, 2010 WL 2507791, at \*19. <sup>4/</sup>

Turning to the appropriate legal standard, the special master agreed with respondent that the “general reliability requirement of Daubert” applies to the special master’s adjudication of vaccine petitions, Veryzer I, 2010 WL 2507791, at \*5, which requires that

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<sup>4/</sup> See de Bazan, 539 F.3d at 1352 n.4 (“Daubert is inapposite here because the special master did not exclude any expert evidence under Daubert. Rather, the special master admitted and weighed both parties’ evidence but simply decided that the government’s evidence was more persuasive.”); Munn, 970 F.2d at 870 n.10 (“[Standards of review applicable to special master’s decisions] vary in application as well as degree of deference. Each standard applies to a different aspect of the judgment. Fact findings are reviewed by us, as by the Claims Court judge, under the arbitrary and capricious standard; legal questions under the ‘not in accordance with law’ standard; and discretionary rulings under the abuse of discretion standard. The latter will rarely come into play except where the special master excludes evidence.”). The special master also cited as confirmation the Supreme Court’s post-Daubert opinion, Kumho Tire Co. v. Carmichael, 526 U.S. 137 (1999), which held that “a court of appeals is to apply an abuse-of-discretion standard when it review[s] a trial court’s decision to admit or exclude expert testimony,” id. at 152 (alteration in original) (citation omitted) (internal quotation marks omitted).

special masters “eschew unreliable evidence, in whatever procedural form that may take,” id. at \*21 (citing Libas, Ltd. v. United States, 193 F.3d 1361 (Fed. Cir. 1999); Terran, 195 F.3d 1302). The special master thus held that, while “there is justly a recalcitrance within the Vaccine Program to exclude evidence,” he may nevertheless “exclude unreliable evidence where the Court is persuaded to a preponderance that it is unreliable.” Id. at \*21. This standard is satisfied “only where an expert’s methodology is so divergent from the scientific method as to be nonsensical and confusing as a whole,” or, put another way, exclusion is proper “only . . . where the material sought to be excluded is so unreliable, it patently forfeits every trace of being helpful to the Court’s consideration of the facts of the case.” Id. (“[A] merely dubious conclusion or a lopsided weighing of evidence does not satisfy the standard of exclusion.”).

The special master did not flinch when applying this standard to petitioner’s proffered experts. He found that Dr. Moulden’s opinions are so unreliable as to warrant exclusion from the record. Dr. Moulden’s methodology “diverges (even veers) from accepted medical science on . . . a fundamental level,” and his opinion lacks a “single indicium of reliability” such that his report “would manifestly be unhelpful” to the special master’s determination. Id. at \*25. Exclusion in this instance is warranted because Dr. Moulden “openly flaunts that he does not follow generally accepted medical science,” and cited Dr. Moulden’s rejection of Pasteur’s germ theory, his belief that “‘all vaccines are useless,’ and that vaccines are the primary pathogen in the world.” Id. at \*22 (“As the Supreme Court stated in Kumho Tire, a reliable expert must adhere to ‘the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.’” (quoting Kumho Tire Co. v. Carmichael, 526 U.S. 137, 152 (1999))).

More critically, the special master found that Dr. Moulden failed to demonstrate how the Hepatitis A vaccine might have caused petitioner’s injuries. Id. at \*23 (“To the extent he discussed this at all, [Dr. Moulden] guarded his opinion on these matters as proprietary and secret.”). The special master noted that Dr. Moulden’s only offer of proof to support his theory of vaccine-caused injuries is petitioner’s (as well as many other’s) eye and face muscle patterns that purport to show “several small ischemic events (strokes) in the brain, based on a postulated inability of white blood cells, multiplied and activated in response to the vaccine, to traverse small blood vessels.” Id. at \*24. Dr. Moulden concludes that the small strokes “cause sundry and different injuries (depending on the individual), but completely without explanation or evidence: not a clue as to how this hypothesis could be observed or tested physically.” Id. (noting, as well, that petitioner’s response to respondent’s objection merely “recapitulated Dr. Moulden’s theory,” without any other “reasoned defense,” which is “actually rather shocking that Petitioner would not only proffer such a fatuous opinion in the first place, but would rise to the defense of mere twaddle”).



Petitioner sought to minimize the import of Dr. Moulden's lack of medical experience or expertise in neurology by emphasizing the expert's research. The special master resisted such finesse by pointing out that none of Dr. Moulden's theories have been subject to testing, duplication of results, and falsifiability because his research has not been published. Id. at \*23. 5/ Due to Dr. Moulden's "recalcitrant" attitude towards disclosing the research and methodology underlying his MASS response theory to the special master or to peer review, the special master characterized Dr. Moulden's opinion as mere *ipse dixit*. Id. Finally, the special master rejected petitioner's premise that Dr. Moulden's opinion is reliable because his conclusions were the result of differential diagnosis, instead finding that Dr. Moulden failed to perform a correct differential diagnosis. Id. at \*24.

Turning to Dr. Tenpenny, the special master found that she lacked a "demonstrated level of expertise that would qualify her to opine" on petitioner's injuries. Id. at \*25. The special master reasoned that Dr. Tenpenny is a doctor of osteopathy, who "was (for a time) a practicing, board-certified doctor of emergency medicine," id., which do not constitute the requisite qualifications necessary to offer a reliable opinion as to the neurological conditions that she ascribed to petitioner, MS or ADEM. Id. (noting that the basis for Dr. Tenpenny's (alternative) MS diagnosis was the expert report filed by Dr. Girard earlier in the litigation, "not her own expertise"). Dr. Tenpenny could not declare definitively that petitioner's injuries were indicative either of MS or ADEM, and the "wide difference between the causes, development, phase, and other elements of pathology in each illness" revealed that "Dr. Tenpenny is overmatched by the subject matter." Id.

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5/ Regarding Dr. Moulden's unconventional publications, the special master concurred with respondent, stating:

As Respondent summarized his statements, "Dr. Moulden will not be describing his findings in a scholarly peer-reviewed scientific journal; rather, his 'findings' will be 'partially released to 6 people/groups' in '6 red envelopes.'" Dr. Moulden's *Curriculum Vitae* lists several publications, which might support or disparage his theory, except that they are in fact unpublished manuscripts listed as "in prep" or "intellectual property," either awaiting publication or being held indefinitely from publication by Dr. Moulden. Respondent concluded on this point that "Dr. Moulden's theory regarding the existence of a 'MASS' response has not been, and most likely never will be, subjected to peer review."

Veryzer I, 2010 WL 2507791, at \*6 (footnote omitted) (citations omitted).

Moreover, Dr. Tenpenny neither explained how the Hepatitis A vaccine caused petitioner's conditions, nor even referred to petitioner's medical records, failures that render her report "thoroughly worthless" and "not relevant enough, to be admissible." Id. at \*26. As with Dr. Moulden, the special master found that Dr. Tenpenny did not engage in a proper differential diagnosis, contrary to petitioner's argument. Id. ("Nowhere in her report did she consider other specific diagnoses, weigh each according to their correspondence with Petitioner's course, and settle on one based on reason."); see also id. at \*26 n.31 (explaining that temporal association alone is not sufficient proof of causation in fact (citing Grant v. Sec'y of Health & Human Servs., 956 F.2d 1144, 1148-49 (Fed. Cir. 1992))). Having excluded the expert opinions of both Drs. Moulden and Tenpenny, the special master ordered petitioner to find a "credibly qualified, methodologically reliable expert" to opine on petitioner's claim that the Hepatitis A vaccine caused his injuries. Id. at \*27.

After petitioner declined to submit additional expert materials, on June 7, 2010, he moved for a ruling on the written record. Veryzer II, 2010 WL 5185485, at \*1. On August 9, 2010, the special master granted petitioner's request and issued a ruling on the written record denying compensation. The special master found that the record submitted by petitioner lacked "substantiating proof of the types of statutorily-required and amounting to a preponderance of the evidence." Id. After reviewing petitioner's medical records, the special master found that the records "mention, but do not in any way support, a causative connection between the Hepatitis A vaccination administered and the injuries suffered under an actual causation burden of proof." Id. at \*3. Because petitioner did not file another medical expert report "of sufficient scientific methodology and validity," the record did not establish a plausible medical theory causally connecting the vaccination to the alleged injuries by a preponderance of the evidence. Id. (citing Pafford v. Sec'y of Health & Human Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006); Althen, 418 F.3d at 1278; Shyface v. Sec'y of Health & Human Servs., 165 F.3d 1344, 1352 (Fed. Cir. 1999); Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 549 (Fed. Cir. 1994)). Therefore, petitioner did not show an entitlement to compensation. Id. at \*4.

Petitioner filed his motion for review on September 7, 2010, to which respondent filed its response on October 7, 2010. The case was transferred to the undersigned on December 6, 2010. Petitioner argues, *inter alia*, that the special master acted arbitrarily and capriciously by failing to make any reference to petitioner's injuries and his almost 500 pages of medical history, which are "directly relevant" to petitioner's claim. Pet'r's Br. filed Sept. 7, 2010, at 2-3. In particular, the special master did not discuss the "onset of petitioner's symptoms" following the vaccinations. Id. at 2. Moreover, the order excluding petitioner's expert opinions or the decision on compensation did not refer to petitioner's affidavit. Id. at 4. Petitioner contends that his medical records show that he was healthy before being vaccinated, establish the temporal relationship between his vaccinations and the onset of

symptoms, and substantiate his “progressive cognitive impairments,” which satisfy petitioner’s burden to show causation between the Hepatitis A vaccine and his injuries. Id. at 4-5. Finally, petitioner argues that the special master employed an overly strict construction of Daubert and erred as a matter of law in not admitting petitioner’s expert opinions on the ground of unreliable methodology because both proffered theories of causation that are “reasonably plausible.” Id. at 5. According to petitioner, the special master engaged in impermissible credibility determinations as a pretext to reject the expert’s various causation theories, id. at 7, and abused his discretion in denying petitioner’s request for an evidentiary hearing to “elucidate the experts’ theories,” id. at 8.

## DISCUSSION

### I. Standards

#### 1. Standard of review

The Vaccine Act specifies three alternative courses of action available to the Court of Federal Claims in reviewing a special master’s decision. The court may

- (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master’s decision,
- (B) set aside any findings of fact or conclusions of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law and issue its own findings of fact and conclusions of law, or
- (C) remand the petition to the special master for further action in accordance with the court’s direction.

42 U.S.C. § 300aa-12(e)(2). The special master’s findings of fact are reviewed under the deferential “arbitrary and capricious” standard. See id. § 300aa-12(e)(2)(B); de Bazan, 539 F.3d at 1350-51; Lampe v. Sec’y of Health & Human Servs., 219 F.3d 1357, 1360 (Fed. Cir. 2000) (explaining that arbitrary and capricious standard is “particularly” difficult to satisfy when issue “turns on the weighing of evidence by the trier of fact”); Munn, 970 F.2d at 870 (noting that arbitrary and capricious standard is “well understood to be the most deferential possible”). In contrast, the special master’s conclusions of law are reviewed without deference. Cedillo v. Sec’y of Health & Human Servs., 617 F.3d 1328, 1338 (Fed. Cir. 2010); Munn, 970 F.2d at 870 (explaining “[i]ssues of law—constitutional imperatives, statutory construction, procedural requirements—come to [the Federal Circuit] for decision with little if any deference owed to or expected by the forums below”). Discretionary

rulings, such as the exclusion of evidence, are reviewed under the abuse of discretion standard. Cedillo, 617 F.3d at 1338; Munn, 970 F.2d at 870 n.10.

## 2. Proving causation in Vaccine Act cases

To be compensated under the Vaccine Act, petitioners must prove that an injury was caused by a vaccine listed on the Vaccine Injury Table set forth in 42 U.S.C. § 300aa-14. See id. § 300aa-11(c)(1)(A),(C); de Bazan, 539 F.3d at 1351. The Vaccine Injury Table, 42 U.S.C. § 300aa-14(a), “lists symptoms and injuries associated with each listed vaccine and a timeframe for each symptom or injury.” de Bazan, 539 F.3d at 1351. Petitioners can meet the causation burden in one of two ways. Walther v. Sec’y of Health & Human Servs., 485 F.3d 1146, 1149 (Fed. Cir. 2007). If petitioners demonstrate that the injury falls under the Vaccine Injury Table within the time frame prescribed by the Table (a “Table injury”), causation is presumed. See 42 U.S.C. § 300aa-14(a); Walther, 485 F.3d at 1149. Alternatively, if the injury is not included on the Vaccine Injury Table, or falls outside the prescribed time frame for the symptom to occur, petitioners must prove by a preponderance of the evidence that the vaccine was the cause in fact of the injury (an “off-Table” injury). See 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I); Walther, 485 F.3d at 1149; see also Shyface, 165 F.3d at 1350. Causation in fact is established by demonstrating by preponderant evidence 1) a medical theory causally connecting the vaccination and the injury; 2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and 3) a showing of the proximate temporal relationship between the vaccination and injury. Althen, 418 F.3d at 1278; see also Broekelschen v. Sec’y of Health & Human Servs., 618 F.3d 1339, 1345 (Fed. Cir. 2010); Moberly v. Sec’y of Health & Human Servs., 592 F.3d 1315, 1322 (Fed. Cir. 2010). Once petitioners meet their burden of proving causation in fact, thereby establishing a prima facie case for entitlement, the burden shifts to respondent to prove that the injury was caused by factors unrelated to the administration of the vaccine. 42 U.S.C. § 300aa-13(a)(1)(B); de Bazan, 539 F.3d at 1352.

## II. The special master’s decision granting respondent’s motion to exclude

### 1. Daubert applies in Vaccine Act proceedings

The court begins its analysis by noting that petitioner does not contest the special master’s authority to exclude expert opinions. See Pet’r’s Br. filed Sept. 7, 2010, at 5-8; Veryzer I, 2010 WL 2507791, at \*8 (“On the issue of the legal standard governing the Court in ruling on Respondent’s Motion, Petitioner essentially stipulates to Respondent’s analysis of the case law, from FRE 702, on to Daubert, then to Terran, concluding that ‘Daubert has been held to provide special masters with a helpful analytical framework for assessing the reliability of the evidence presented in vaccine cases.’” (citation omitted)). Because the

nature and extent of this authority bear on its exercise, which is contested, the court states its agreement with the special master's analysis of the issue and his conclusion that he possesses discretionary authority to exclude from the record expert evidence deemed unreliable. In Munn the Federal Circuit observed that discretionary rulings are viewed on appeal under the abuse of discretion standard, which "rarely will come into play except where the special master excludes evidence." Munn, 970 F.2d at 870 n.10. This authority is rooted in the Vaccine Act, which invests the special master with discretionary authority to exclude from the record—as "established by the special master," 42 U.S.C. § 300aa-13(c)—evidence that is not "relevant medical and scientific evidence," id. § 300aa-13(b)(1). Vaccine Rule 8 implements this statutory grant of authority, providing that the special master must "consider all relevant and reliable evidence." Vaccine R. 8(b)(1). The special master cited Daubert as "a transferable concept" for reliability, correctly noting that the "specific locus" of which was "the exclusionary rule of FRE 702," which is inapplicable to Vaccine Act cases. Veryzer I, 2010 WL 2507791, at \*21.

Despite the genesis of Daubert in the Federal Rules of Evidence, it is well-settled law that special masters may look to Daubert's four factors when weighing the reliability of expert opinion evidence already admitted. 6/ See Cedillo, 617 F.3d at 1339 ("We have previously held that Special Masters may look to the Daubert standards in evaluating expert testimony. . . . It is thus quite clear that the Daubert factors may be used in vaccine cases to assess expert witnesses' methodology . . ."). However, Daubert's application to exclude evidence is less settled. See Terran, 195 F.3d at 1316 (holding that special masters may analyze proffered expert testimony according Daubert, using its four factors "as a tool or framework for conducting the inquiry into the reliability of the evidence"); Snyder v. Sec'y of Health & Human Servs., 88 Fed. Cl. 706, 737 (2009) ("In cases filed under the Vaccine Act, where the rules of evidence do not apply, Daubert does not generally serve as a basis to exclude expert testimony, but rather, a framework to weigh and evaluate testimony." (quoting Snyder v. Sec'y of Health & Human Servs., No. 01-162V, 2009 WL 332044, at \*138 (Fed. Cl. Spec. Mstr. Feb. 12, 2009))). But see Ryman v. Sec'y of Dep't of Health & Human Servs., 65 Fed. Cl. 35, 40 (2005) ("In Daubert, the Supreme Court assigned the trial judge a 'gate-keeping' function to ensure the reliability of evidence presented to the trier-of-fact. The [special master], of course, performs this same function when he determines

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6/ The four Daubert factors for determining the admissibility of expert opinion, as established by the Federal Circuit in Cedillo, are "(1) general acceptance in the scientific community; (2) whether the theory has been subjected to peer review and publication; (3) whether the theory can and has been tested; and (4) whether the known potential rate of error is acceptable." Cedillo, 617 F.3d at 1339 (citing Daubert, 509 U.S. at 593-94).

whether a particular petitioner's expert medical testimony supporting biologic probability may be admitted or credited or otherwise relied upon.”).

Considering that special masters may use Daubert when weighing the reliability of proffered expert opinion in a merits determination, and are bound by both § 300aa-13(b)(1) and Vaccine Rule 8(b)(1) to consider only evidence that is both “relevant” and “reliable,” it makes eminent sense to look to Daubert when determining whether to admit or exclude proffered expert testimony or reports. As the special master noted, “it is a settled point of law that binds this Court to eschew unreliable evidence, in whatever procedural form that may take.” Veryzer I, 2010 WL 2507791, at \*21 (noting that “the principle of reliability as a precondition of reliance is a transferable concept”); see Cedillo, 617 F.3d at 1339 (explaining that “terms ‘relevant and reliable,’ [in] Vaccine Rule 8(b)(1) necessarily contemplates an inquiry into the soundness of scientific evidence to be considered by special masters,” and holding that special master did not error in applying Daubert “in evaluating the reliability of the parties’ scientific evidence”); Moberly, 592 F.3d at 1324 (“[T]he special master is entitled to require some indicia of reliability to support the assertion of the expert witness.” (citing, *inter alia*, Daubert, 509 U.S. 579)); Whitecotton v. Sec’y of Health & Human Servs., 81 F.3d 1099, 1108 (Fed. Cir. 1996) (“Congress desired the special masters to have very wide discretion with respect to the evidence they would consider and the weight to be assigned that evidence.” (emphasis added)); Perreira v. Sec’y of Dep’t of Health & Human Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (“An expert opinion is not better than the soundness of the reasons supporting it.”); cf. Uniloc USA, Inc. v. Microsoft Corp., No. 2010-1035, slip op. at 42-43 (Fed. Cir. Jan. 4, 2011) (applying Daubert and Kumho Tire under Fed. R. Evid. 702 in patent opinion, and stating “[i]f the patentee fails to tie the theory to the facts of the case, the testimony must be excluded”); Libas, 193 F.3d at 1366 (“Daubert and Kumho were decided in the context of determining standards for the admissibility of expert testimony under the Federal Rules of Evidence, which are not at issue here. We agree with [petitioner], however, that the proposition for which they stand, that expert testimony must be reliable, goes to the weight that evidence is to be accorded as well as to its admissibility.” (emphasis added)).

## 2. Whether the special master abused his discretion

Petitioner submits that the special master's construction of Daubert was overly strict and that he erred as a matter of law in not admitting petitioner's expert opinions on the ground of unreliable methodology when both experts proffered theories of causation that are “reasonably plausible.” Pet'r's Br. filed Sept. 7, 2010, at 5. Petitioner submits that the special master engaged in impermissible credibility determinations as a pretext to reject the experts' various causation theories in contravention of Andreu v. Secretary of Health and Human Services, 569 F.3d 1367, 1379 (Fed. Cir. 2009), which held that special masters

cannot “cloak the application of an erroneous legal standard in the guise of a credibility determination.” For the reasons set forth below, the court disagrees. The special master’s decision granting respondent’s motions *in limine* is an admirably intellectual and careful review of the law and of the experts’ reports and credentials.

Indeed, petitioner took a calculated risk in proffering the opinion of Dr. Moulden, who does not follow the methods accepted by medical science and outright rejects the scientific method. See Moulden Report at 90-91 (rejecting Pasteur’s germ theory and describing all vaccines as “useless”). The special master was charitable in noting that this opinion “diverges from the understanding of acceptable medical science, not least in the field of immunology.” Veryzer I, 2010 WL 2507791, at \*22. Further, the court agrees with the special master’s assessment that rejecting germ theory in toto fatally undermines any ascription of reliability to Dr. Moulden’s opinion because those matters “affect the very fiber of scientific methodology,” id., and are contrary to the Supreme Court’s instruction that a reliable expert must “employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field,” Kumho Tire, 526 U.S. at 152.

Notably, the special master explained that he was not penalizing Dr. Moulden merely for postulating an unorthodox theory. See Veryzer I, 2010 WL 2507791, at \*22 n.25 (“To be clear, the Court is not prejudicing Dr. Moulden for having an opinion outside the mainstream current of medical scientific thought. His opinion that ‘The entire medical model is both flawed and incorrect,’ however, was made without a scintilla of logical or scientific support, and that is the reason for the Court’s disregard for his opinion at this point (among others).”). Dr. Moulden did not submit for peer review (or to the special master) his research supporting his M.A.S.S. response theory of causation linking the Hepatitis A vaccine to petitioner’s injuries; instead he “guarded his opinion on these matters [as] proprietary and secret.” Id. at \*23. Petitioner offers no response to the special master’s findings that Dr. Moulden failed to submit his research for publication within the medical field or release the results of his research. It is not an “overly strict construction of [Daubert,]” Pet’r’s Br. filed Sept. 7, 2010, at 5, to require that Dr. Moulden’s methodology correspond to a single Daubert factor, see Veryzer I, 2010 WL 2507791, at \*23 (“Furthermore . . . the absence of publication within the medical field also makes testing, duplication of results, and falsifiability impossible for others to perform.”).

The court similarly finds no error in the special master’s decision regarding Dr. Tenpenny. The special master rejected Dr. Tenpenny on the reasonable ground that she lacked the requisite expertise in neurology, which, considering her theories of either MS or ADEM, is the subject upon which petitioner asked her to opine. See Veryzer I, 2010 WL 2507791, at \*25. As the special master noted, Dr. Tenpenny’s experience and background are in emergency medicine, not neurology. Beyond repeating Dr. Tenpenny’s conclusions,

petitioner offers no response to the special master's finding that Dr. Tenpenny failed to explain how the Hepatitis A vaccine caused petitioner's injuries or definitively choose between the theories of MS and ADEM. See id. at \*25-26. Petitioner does not point to any specific fault in the special master's determination that the methodology employed by the two experts was unreliable, other than simply to restate the three conflicting theories of causation offered by the experts. In fact, had the special master accepted the reliability of Dr. Moulden, as a point of logic, he necessarily would be rejecting the reliability of Dr. Tenpenny, as she at least adheres to traditional medical models that are the subject of Dr. Moulden's derision.

The special master's discretionary rulings are overturned only if petitioner demonstrates an abuse of discretion. See Munn, 970 F.2d at 869. The special master's exclusion of petitioner's expert opinions cannot be regarded as an improper credibility determination, nor was it merely the result of "distaste" for their opinions. See Pet'r's Br. filed Sept. 7, 2010, at 7. Instead, as respondent submits, they were excluded based on "the methodological flaws and lack of any substantive support provided by either expert." Resp.'s Br. filed Oct. 7, 2010, at 12. The special master's determinations are supported by precedent from the Federal Circuit:

While Daubert does not require that the expert's ultimate conclusions be generally accepted in the scientific community, and the focus on a Daubert inquiry must generally be "on principles and methodology, not on the conclusions they generate," "conclusions and methodology are not entirely distinct from one another . . . . A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered."

Cedillo, 617 F.3d at 1339 (alteration in original) (quoting Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997)). Too great an analytical gap is precisely what the special master found. His decision was well reasoned and not an abuse of discretion.

### 3. The special master's exclusion of expert opinions without a hearing

Petitioner challenges the special master's denial of his request for an evidentiary hearing, contending that excluding the opinions of Drs. Moulden and Tenpenny without a hearing to assess their credibility was an abuse of discretion. The Vaccine Act commits to the special master the decision to hold an evidentiary hearing. See 42 U.S.C. § 300aa-12(d)(3)(B)(iii), (v) ("In conducting a proceeding on a petition a special master . . . may require the testimony of any person and the production of any documents as may be reasonable and necessary . . . [and] may conduct such hearings as may be reasonable and necessary."). Similarly, Vaccine Rule 8 provides that the special master "may conduct an



evidentiary hearing to provide for questioning of witnesses,” Vaccine R. 8(c)(1), and may “decide a case on the basis of written submissions without conducting an evidentiary hearing,” Vaccine R. 8(d). Both provisions use the discretionary word “may,” so the decision not to hold a hearing squarely falls within the discretion of the special master.

In this case the special master observed that “both parties have expressed themselves fully herein, as certainly as Dr. Moulden did in his lengthy report,” Veryzen I, 2010 WL 2507791, at \*7 n.12, and, after a detailed opinion that thoroughly analyzed the opinions and credentials of both experts, he deemed the evidence to be so “patently unreliable” that a hearing would be a waste of time and resources, id. at \*26. The court concludes that the special master’s denial of petitioner’s evidentiary hearing request was not an abuse of discretion.

### III. The special master’s decision denying compensation

The Vaccine Act requires the special master to “issue a decision on [each] petition with respect to whether compensation is to be provided under the Vaccine Program . . . . The decision of the special master shall . . . include findings of fact and conclusions of law.” 42 U.S.C. § 300aa-12(d)(3)(A)(I). Additionally, the Vaccine Act sets forth, as a “[g]eneral rule”:

#### **§ 300aa-13. Determination of eligibility and compensation**

##### **(a) General rule**

(1) Compensation shall be awarded under the [Vaccine] Program to a petitioner if the special master or court finds on the record as a whole—

(A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 300aa-11(c)(1) of this title, and

(B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.

The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.

42 U.S.C. § 300aa-13(a)(1).

Having excluded the experts' theories of causation, the special master afforded petitioner another opportunity to find an expert whose opinion could support his burden to establish "a medical theory causally connecting the vaccination and the injury." Althen, 418 F.3d at 1278; see also Veryzer I, 2010 WL 2507791, at \*27. Petitioner declined and requested that the special master rule on the written record. Petitioner now contends that the special master did not consider his medical records and affidavit. Petitioner's motion for review suggests that his affidavit, which details petitioner's progressively more severe injuries, see generally Affidavit of Petitioner Robert Veryzer, undated, ECF No. 41 (Fed. Cl. Spec. Mstr.), and the close temporal proximity between administration of the Hepatitis A vaccination and the onset of his "progressive cognitive impairments," as set forth in his medical records, satisfy petitioner's burden to establish causation, see Pet'r's Br. filed Sept. 7, 2010, at 4-5.

The special master found, as follows:

In this case, the medical records mention, but do not in any way support, a causative connection between the Hepatitis A vaccination administered and the injuries suffered under an actual causation burden of proof. Under the statute, the Court cannot grant a petitioner compensation based solely on the petitioner's asseverations [his affidavit]. Rather, the petition must be supported by either medical records or by the opinion of a competent physician. 42 U.S.C. § 300aa-13(a)(1). Here, because the medical records do not manifestly support the petitioner's claim of vaccine causation, a medical opinion of sufficient scientific methodology and validity must be offered in support. No medical expert opinion report meeting that standard was filed by Petitioner to support the claims of causation within the Petition to a preponderance of the evidence, and Petitioner therefore did not surmount the standard set by the settled law on this point. Accordingly, the information on the record extant does not show entitlement to an award under the [Vaccine] Program.

Veryzer II, 2010 WL 5185485, at \*3. The special master explained that the medical records petitioner filed were "absent" of a "detailed analysis of the Record to indicate a logical sequence of cause and effect showing that the vaccination was the reason for the injury" and that, therefore, petitioner had not offered a "theory of causation as such." Id. at \*4 (internal quotation marks omitted).

The problem, however, is that the special master did not make findings of fact concerning the medical records. Respondent conflates sections 12 and 13 to make the inventive, but meritless, argument that the special master can make one finding on the record as a whole. See Resp.'s Br. filed Oct. 7, 2010, at 9 ("Here, the special master's Decision plainly satisfies the requirements of the Act, by stating that after considering the medical records, he found as a matter of fact that they did not support petitioner's claim of vaccine causation."). Of course, the former provision requires findings of fact, while the latter provision conditions eligibility to an award on a finding "on the record as a whole."

The 500-odd pages of medical records portray petitioner's cognitive decline over an eighteen-month period following petitioner's April 25, 2001 Hepatitis A vaccination. Petitioner became fixated on erectile dysfunction, then a scar that he attributed to the vaccine, then his inability to focus and function professionally. A score of medical professionals expressed as much concern with his mental state as his physical symptoms and their etiology. Finally, beginning in March 2002, petitioner linked with doctors who ascribed his deteriorated condition to elevated levels of mercury. One treating physician specifically instructed: "**Check for Aluminum, lead, mercury, arsenic and cadmium intoxication** (in serum and in urine 24 hours) in the context of this type symptomatology after Hepatitis vaccination." Pet'r's Med. R. filed Mar. 9, 2007, at 393, ECF No. 18 (Fed. Cl. Spec. Mstr.).

The medical records offer inconsistent indications of possible causes, which the fact finder may deem inconclusive and not a demonstration of a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." Althen, 418 F.3d at 1278. Petitioner has shown a "temporal relationship" between his vaccinations and the first manifestation of his injuries. See id. However, this singular showing is not sufficient to establish causation in fact without addressing the two remaining factors. See Grant, 956 F.2d at 1148 ("When a petitioner relies upon proof of causation in fact rather than proof of a Table Injury, a proximate temporal association alone does not suffice to show a causal link between the vaccination and the injury. To prove causation in fact, petitioners must show a medical theory causally connecting the vaccination and the injury.").

Absent a causal connection from the medical records or reliable expert testimony, petitioner's only remaining proof was his affidavit, which he charges the special master failed to review or even mention. The special master correctly adduced that compensation cannot be granted "based solely on the petitioner's asseverations," Veryzer II, 2010 WL 5185485, at \*3, i.e., based solely on petitioner's affidavit, see 42 U.S.C. § 300aa-13(a)(1) ("The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion."). Whatever weight the special master accorded petitioner's affidavit is immaterial.

Nonetheless, contrary to the requirements of the Vaccine Act, the special master failed to make factual findings that adequately articulate his reasons for concluding that petitioner's medical records are insufficient to establish a medical theory causally connecting petitioner's injuries to the Hepatitis A vaccination. See 42 U.S.C. § 300aa-12(d)(3)(A)(I) ("The decision of the special master shall . . . include findings of fact and conclusions of law."). Fairness and equity require more than a single finding on the record as a whole.

The undersigned judge recently sustained a special master's decision denying compensation and dismissing a petition in Simanski v. Secretary of Health and Human Services, No. 03-103V, slip op. at 33 (Fed. Cl. Dec. 15, 2010) ("Simanski II"), wherein the petitioners claimed, *inter alia*, that the special master failed to review the record as a whole, including 24,835 pages of medical records and an affidavit, see id. at 30. Simanski is distinguishable from the instant case.

First, in the case at bar, petitioner's medical records "mention . . . a causative connection between the Hepatitis A vaccination administered and the injuries suffered." Veryzer II, 2010 WL 5185485, at \*3. In Simanski, the special master explained: "Here it appears that the medical records do not support the petitioners' claim for compensation in that petitioners have not identified any treating doctor who opined that Olivia's condition was caused by a vaccination." Simanski v. Sec'y of Health & Human Servs., No. 03-103V, 2010 WL 2292200, at \*12 (Fed. Cl. Spec. Mstr. May 13, 2010) ("Simanski I"). Second, petitioner in this case points to specific medical records that he contends the special master failed to consider. See Pet'r's Br. filed Sept. 7, 2010, at 2-4. In Simanski, the petitioners failed to identify any specific medical record that established causation and that the special master did not consider. See Simanski II, slip op. at 33.

While the special masters are not required to list every document reviewed, the special master's findings in Simanski demonstrated a review of the petitioner's medical records. See id. at 30-31 (noting special master's recitation of petitioner's medical history "is replete with references to her medical record"). The special master in the instant case failed to explain on any level why petitioner's medical records "do not manifestly support the petitioner's claim of vaccine causation." Veryzer II, 2010 WL 5185485, at \*3. <sup>7/</sup> In contrast, the special master's denial of compensation in Simanski II was based on the sufficiency of petitioners'

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<sup>7/</sup> The court does not take the special master's statement to articulate a standard, because, under Althen, it would be incorrect. Rather, the adverb "manifestly" appears to have been misplaced, i.e., "petitioner's medical records manifestly do not support causation." Whatever the intended meaning of "manifestly," the special master did not make adequate findings of fact.

expert opinions in the record as a whole. In this case, once the special master excluded petitioner's expert reports, the decision was based on the contents of the petitioner's medical records. See generally Simanski I, 2010 WL 2292200, at \*2-5. More importantly, the court's decision in Simanski was limited to the procedural question of whether the special master had authority to dismiss a petition for failure to comply with a special master's show cause order requiring the petitioners to submit a sufficient expert medical opinion. See Simanski II, slip op. at 32 ("What is presented in the instant case is a ruling on a procedural issue . . .").

The court contrasts these two reviews because they underscore the impropriety of the Court of Federal Claims' making factual findings in the first instance on an array of medical records that were not argued to the special master. The court can review a special master's exclusion of evidence, i.e., the two expert opinions, which is a quintessential review function. However, it cannot make findings on an agglomeration of medical records that were submitted with a petition. Not only was there no record to review of what either petitioner or respondent sought to glean from the medical records (petitioner requested a decision on the record as a whole), but the potentially revelatory discussions between the special master and the parties concerning the evidence were off the record and not memorialized in any subsequent order. In short, the "record" before the special master that is before the Court of Federal Claims on a motion for review in this case is not a record amenable to judicial review when it consists of documentation submitted in support of a petition without a record of both argument of counsel to the special master about what the medical records do or do not establish and findings by the special master thereon. See generally Simanski II, slip op. at 31-33.

## CONCLUSION

The court has carefully considered petitioner's remaining arguments and deems them without merit. The court concludes that the special master did not abuse his discretion by excluding petitioner's expert opinions, but that the special master did not make adequate findings concerning petitioner's medical records. Accordingly, based on the foregoing,

**IT IS ORDERED**, as follows:

1. Pursuant to 42 U.S.C. § 300aa-12(e)(2)(C), this matter is remanded to the office of special masters for assignment to a new special master (the incumbent having retired), who shall include findings of fact and conclusions of law concerning petitioner's medical records. The special master may reopen the record if he/she deems it reasonable and necessary.

2. The decision on remand shall be issued by May 2, 2011.

/s/ Christine O.C. Miller

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**Christine Odell Cook Miller**  
Judge